

19. (Original) The kit of claim 16, wherein said reagents include at least one organic solvent, nuclease free water, RLT buffer, and RPE buffer.

20. (New) The method of claim 1, wherein said one or more DNase enzymes is selected from the group consisting of DNase I, DNase II, and a combination thereof.

21. (New) The method of claim 1, wherein said chaotropic salt is selected from the group consisting of guanidine isothiocyanate, ammonium isothiocyanate, guanidine hydrochloride, and a combination thereof.

Remarks

Claims 1 through 19 are pending in this application. Pursuant to a Restriction Requirement, claims 1 through 15 are currently being prosecuted.

Petition

The Examiner states that the Petition for color drawings is objected to because the paragraph in the Specification regarding color drawings must be the first paragraph of the brief description of the drawings.

Applicants are considering whether it is necessary to employ color photographs or whether black/white photographs can depict the data sufficiently. Should Applicants decide to use color photographs, then an appropriate amendment will be made to the Specification.

Claim Rejections under 35 USC § 112

Claims 2-6 and 14-15 are rejected under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The Examiner states that claims 2-6 are indefinite in the recitations "BTS," "PVDF," "MMM," and "PVP," because they are acronyms, the meanings of which may change over time.

Applicants contend that these acronyms are terms well recognized by those skilled in the art and are well understood at the time of filing the present application. However, for the purpose of accelerating prosecution, Applicants have amended claims 2 and 4.

Applicants contend that the amendments presented above should obviate this rejection under 35 USC § 112. Thus, Applicants respectfully request reconsideration and withdrawal of the present rejections.

Claim Rejections under 35 USC § 103

1) Claims 1 and 14-15 are rejected under 35 USC 103(a) as being unpatentable over Coplan et al (US Pat. No. 6,383,393 B1) in view of Sutcliffe et al (US Pat. No. 5,459,037).

The Examiner states that Coplan et al teach a method of preparing an RNA sample substantially free of contaminants. However, the Examiner adroitly points out that Coplan et al fail to teach the preparation of cRNA. The Examiner contends that Sutcliffe et al teach a method comprising the preparation of cRNA. Hence, the Examiner concludes, it would have been obvious to one skilled in the art to modify the method of Coplan et al with cRNA as taught by Sutcliffe et al. Applicants respectfully disagree.

In order to establish a *prima facie* case of obviousness, "there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references) must teach or suggest all of the claim limitations." M.P.E.P. §2143, see also, *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The presently claimed invention is directed toward a method for preparing cRNA from a sample by preparing a cRNA sample, then adding an organic solvent to that preparation, followed by contacting an isolation column with the organic preparation. This step is followed by adding one or more DNase enzymes followed by washing the preparation with a buffer comprising a chaotropic agent. Following this washing step the cRNA can be eluted from the isolation column. (See amended Claim 1.)

Neither Coplan et al nor Sutcliffe et al employ the use of a DNase or chaotropic wash buffer, either alone or in combination. Both citations are silent as to these two elements of the claimed invention, as well as other elements. In order for a reference to be used alone or in combination with another reference to establish obviousness, the references must teach or suggest each and every element of the claimed invention. (Additionally, there must be motivation to combine such references and a reasonable expectation of success at arriving at the claimed invention.) Clearly, Coplan alone or in combination with Sutcliffe meet this legal threshold for obviousness.

Therefore, Applicants respectfully request reconsideration and withdrawal of the present rejection. (It is axiomatic in patent law that should an independent claim define allowable subject matter, then the claims depending therefrom also necessarily define allowable subject matter.)

- 2) Claims 1 and 10-13 are rejected under 35 USC 103(a) as being unpatentable over Coplan et al ('393) in view of Sutcliffe et al ('037).

As stated in the previous argument, claim 1 has been amended adding two additional limitations not found in either Coplan et al or Sutcliffe et al. In addition to other elements not found in either cited reference, these additional elements clearly define this claimed invention outside of the two references cited.

Therefore, Applicants respectfully request reconsideration and withdrawal of the present rejection. (It is axiomatic in patent law that should an independent claim define allowable subject matter, then the claims depending therefrom also necessarily define allowable subject matter.)

- 3) Claims 1-6 are rejected under 35 USC 103(a) as being unpatentable over Coplan et al ('393) and Sutcliffe et al ('037) as defined by Pall Life Sciences and further in view of Wang et al. (US Pat. No. 5,906,742).

As discussed above, claim 1 has been amended to add the limitations DNase enzymes and a chaotropic wash step. Neither of these steps are found in the either Coplan, Sutcliffe or

the added references Pall Life Sciences and Wang et al. As a result, the cited references fail to establish obviousness alone or in combination.

Therefore, Applicants respectfully request reconsideration and withdrawal of the present rejection. (It is axiomatic in patent law that should an independent claim define allowable subject matter, then the claims depending therefrom also necessarily define allowable subject matter.)

4) Claims 1 and 7-9 are rejected under 35 USC 103(a) as being unpatentable over Coplan et al ('393) and Sutcliffe ('037) and further in view of Waggoner (US Pat. No. 5,627,027).

As discussed above, claim 1 has been amended. Neither Coplan, Sutcliffe, nor Waggoner teach or suggest the use of a DNase enzyme. Moreover, these references are silent as to the use of a chaotropic wash following the use of DNase. Therefore, obviousness cannot be established using these references either alone or in combination.

Therefore, Applicants respectfully request reconsideration and withdrawal of the present rejection. (It is axiomatic in patent law that should an independent claim define allowable subject matter, then the claims depending therefrom also necessarily define allowable subject matter.)

Although no fees are required, please charge any underpayment of fees to or credit any overpayment of fees to Deposit Account No. 03-2410.

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The Examiner is invited to call the undersigned attorney at (617) 345-3253 should he determine that a telephonic interview would expedite prosecution of this case.

Respectfully submitted,

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